Meta-Analysis of Comparison Between Self-Expandable and Balloon-Expandable Valves for Patients Having Transcatheter Aortic Valve Implantation

Claudio Moretti, PhD[a], Fabrizio D'Ascenzo, MD[a], Marco Mennuni, MD[b], Salma Taha, MD[a,c,*], Nedy Brambilla, MD[d], Freek Nijhoff, MD[e], Chiara Fraccaro, MD[f], Marco Barbanti, MD[g], Corrado Tamburino, MD[g], Giuseppe Tarantini, MD[f], Marco L. Rossi, MD[b], Patrizia Presbitero, MD[b], Massimo Napodanno, MD[f], Pieter Stella, PhD[e], Francesco Bedogni, MD[d], Pierluigi Omedè, MD[a], Federico Conrotto, MD[h], Antonio Montefusco, MD[a], Francesca Giordana, MD[a], Giuseppe Biondi Zoccai, MD[i], Piefrancesco Agostoni, PhD[e], Maurizio D'Amico, MD[h], Mauro Rinaldi, MD[j], Sebastiano Marra, MD[h], and Fiorenzo Gaita, MD[a]

Two different devices, 1 self-expanding and 1 balloon-expandable, have been developed for patients who underwent transcatheter aortic valve implantation with contrasting data about efficacy and safety. Pubmed, Medline, and Google Scholar were systematically searched for studies of these different devices, with data derived from randomized controlled trial or registries with multivariate analysis. All-cause death at 30 days and at follow-up were the primary end points, whereas postprocedural moderate or severe aortic regurgitation (AR), stroke, major vascular complications, bleedings, and pacemaker implantation the secondary ones. Six studies with 957 self-expanding and 947 balloon-expandable valves were included: 1 randomized controlled trial and 5 observational studies. At 30 days follow-up, rates of death did not differ between self-expanding and balloon-expandable valves (odds ratio [OR] 0.74, 95% confidence interval [CI] 0.47 to 1.17), whereas balloon expandable reduced rates of moderate or severe AR (OR 0.51, 95% CI 0.27 to 0.99) and of pacemaker implantation (OR 0.28, 95% CI 0.17 to 0.47). After a follow-up of 360 days (300 to 390), rates of all-cause death did not differ between the 2 groups. In conclusion, risks of moderate or severe AR and pacemaker implantation were lower with the balloon-expandable devices without an impact on 30 days and midterm mortality. **(Am J Cardiol 2015;115:1720−1725)**

Transcatheter aortic valve implantation (TAVI) now represents an effective strategy for patients with severe aortic stenosis at high risk for surgery, as demonstrated by randomized controlled trials[1,2] and large observational studies.[3] Two devices with different technologies have been developed and tested, that is, self-expanding nitinol prosthesis and balloon-expandable metal ones,[4−6] both of them with excellent results in terms of clinical outcomes.[7] Although self-expanding devices expose patients to more frequent pacemaker implantations, with increased costs but without a negative impact on prognosis,[8] contrasting data have been reported about postimplant aortic regurgitation (AR), one of the most common complications of TAVI, with a well-defined impact on prognosis.[9] Recently, some registries have demonstrated an increased risk of AR for patients treated with self-expanding devices[10,11] as subsequently confirmed by a single randomized controlled trial.[12] These studies, however, are limited by small sample size, not allowing conclusive appraisal about the most efficacious and safe device for patients with TAVI. Consequently, we performed a meta-analysis of randomized controlled trials and adjusted observational studies to compare self-expanding and balloon-expandable devices.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) amendment to the Quality of Reporting of Meta-analyses statement and recommendations from the Cochrane Collaboration and Meta-analysis of Observational Studies in Epidemiology were followed during the development of the present systematic review.[13−15]

[a]Division of Cardiology 1, [h]Division of Cardiology 2, and [j]Division of Cardiac Surgery, Città della Salute e della Scienza Hospital, University of Turin, Turin, Italy; [b]Division of Cardiology, Istituto Humanitas, Milan, Italy; [c]Department of Cardiology, Assuit University Hospital, Assuit, Egypt; [d]Department of Interventional Cardiology, Istituto Clinico S. Ambrogio, Milan, Italy; [e]Cardiology Department, University Medical Center Utrecht, Utrecht, Netherlands; [f]Division of Cardiology, Department of Cardiac, Thoracic and Vascular Sciences, University of Padova, Padova, Italy; [g]Cardiology Department, Ferrarotto Hospital, University of Catania, Catania, Italy; and [i]Department of Medico-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Rome, Italy. Manuscript received January 22, 2015; revised manuscript received and accepted March 1, 2015.

See page 1724 for disclosure information.

*Corresponding author: Tel: (+39) 389-5705195; fax: (+39) 011-2369557.

E-mail addresses: meshmeshaya11@yahoo.com; esmaeil.salma@gmail.com (S. Taha).

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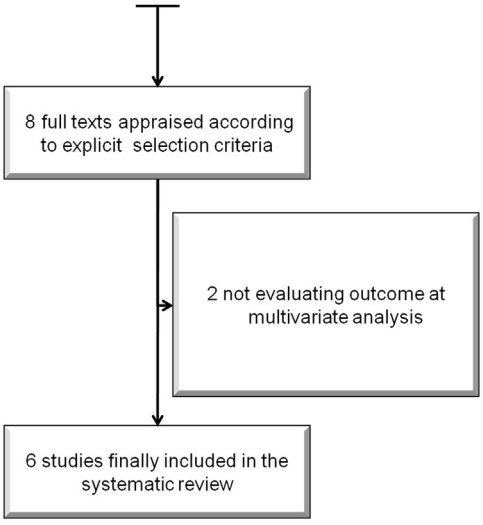


Figure 1. Flow chart.

Pertinent articles were searched for in Medline, Cochrane Library, Biomed Central, and Google Scholar without time limit (up to June 4, 2014) in keeping with established methods with Medical Subject Headings (MeSH) strategy and with the following terms, including "TAVI" or "transcatheter aortic valve implantation" or "self-expandable" or "balloon expandable" or "Corevalve" or "Edwards."

Two independent reviewers (FDA and GBZ) screened the retrieved citations through the title and/or abstract, and divergences were resolved through consensus. If potentially pertinent, studies were then appraised as complete reports according to the following explicit selection criteria. Studies were included if (i) they reported outcomes of patients with TAVI treated with self-expanding or balloon-expandable techniques and (ii) randomized controlled trials or observational studies adjusted with multivariate analysis, whereas exclusion criteria were (i) nonhuman setting and (ii) duplicate reporting (in which case the manuscript reporting the largest sample of patients was selected).

Two independent reviewers (FDA and GBZ) abstracted the following data on prespecified forms: authors, journal, year of publication, location of the study group, and baseline clinical and interventional features. Data extraction was conducted by mutual agreement, and all potential disagreements were resolved by consensus. All-cause death at 30 days and at follow-up were the primary end points, whereas postprocedure moderate or severe AR, stroke, major vascular complications and bleedings, and pacemaker the secondary ones.

Continuous variables are reported as mean (SD) or median (interquartile). Categorical variables are expressed as n/N (%). Statistical pooling was performed according to a random-effect model with generic inverse-variance weighting, computing risk estimates with 95% confidence intervals, using RevMan 5 (The Cochrane Collaboration, The Nordic Cochrane Centre, Copenhagen, Denmark). Pairwise meta-analysis was performed for overall studies, whereas meta-regression analysis was performed to test the effect of baseline features on primary and secondary outcomes. The study was approved by an institutional review committee and that the subjects gave informed consent.

Results

After literature search, 8 full texts were evaluated for inclusion into review: 2 were excluded as they did not report on outcomes adjusted through multivariate analysis[16,17] and finally 6 studies were included[7,10–12,18,19] (Figure 1).

All the studies were multicenter, with a single randomized controlled trial, all of them exploiting balloon-expandable devices of 23 and 26 mm and self-expanding devices of 23, 26, 29, and 31 mm (Tables 1 and 2).

Overall, 957 self-expandable and 947 balloon-expandable valves were included, with a median age of 82 (81 to 83) years, 42% (36 to 53) of them being women, with a median logistic EuroSCORE of 22 (21 to 22). Median annulus diameter was 22 mm (21 to 23); 26-mm devices were implanted in 50% (44 to 51) of the patients, 23 mm in 15% (4 to 18), 29 mm in 33% (31 to 37), and 31 mm in 2% (1 to 2) (Table 3).

At 30 days follow-up, rates of death did not differ between self-expanding and balloon-expandable valves (odds ratio [OR] 0.74, 95% confidence interval [CI] 0.47 to 1.17), whereas balloon expandable reduced rates of moderate or severe AR (OR 0.51, 95% CI 0.27 to 0.99) and of pacemaker implantation (OR 0.28, 95% CI 0.17 to 0.47). Both valves performed similar for major and life-threatening bleedings (24% [16 to 32] vs 27% [20 to 34]; OR 1.40, 95% CI 1.18 to 1.66) and for major vascular complications (6% [3 to 9] vs 9% [5 to 13]; OR 1.17, 95% CI 0.81 to 1.69).

After a follow-up of 360 days (300 to 390), rates of all-cause death did not differ between the 2 groups (15% [11 to 16] vs 13% [12 to 17]; OR 0.95, 95% CI 0.60 to 1.51). At meta-regression analysis, benefit of balloon-expandable valves to reduce AR increased with annulus diameter (beta 0.15, $p < 0.001$; see Figures 2 to 7), whereas other clinical variables were not significantly related to primary and secondary end points.

Discussion

To the best of our knowledge, this is the largest study comparing balloon-expandable and self-expanding devices for patients with TAVI, demonstrating that (a) balloon-expandable prosthesis reduced the rates of moderate and severe AR and of pacemaker implantation; and (b) rates of 30 and 360 days death did not vary.

AR represents one of the most common complications for patients with TAVI.[20–22] Balloon-expandable valves reduced risk of AR compared with self-expanding valves, in studies exploiting second and third generations of currently available devices.

Our results confirmed in a larger population those derived from the only randomized controlled trial on the topic included in the present analysis.[12] Many different explanations have been provided. Burden of aortic calcification may play a crucial role because it may reduce the complete sealing of the paravalvular space. This may be particularly relevant for self-expanding valves, which were recently demonstrated to be inferior regarding radial force,[23] especially for patients with a large angle between ascending aorta and left ventricle outflow tract because of their longer size.[24] Similarly, the results of the meta-regression analysis demonstrated an increased superiority for balloon-expandable devices in

Table 1
Baseline features of included studies

Include reference	Design of the study	Number of centers	Region	Years of enrollement
Abdel-Wahab, 2014[10]	Observational, prospective	2	Europe	2007-2012
Chieffo, 2013[7]	Observational, prospective	3	Europe	2011
Choice, 2014[12]	Randomized controlled	8	Europe	2012-2013
Nombela-Franco, 2013[11]	Observational, prospective	4	North America	2012-2013
D′Ascenzo, 2013[18]	Observational, prospective	5	Europe	2008-2012
Watanabe, 2013[19]	Observational prospective	2	Europe	2008-2012

Table 2
Devices used

Study	Kind of balloon expandable devices	Kind of self expandable devices
Abdel-Wahab, 2014	Edwards SAPIEN XT 23/26 mm Delivery system of 18/19 F	Medtronic Core Valve 26/29 mm Delivery system of 18 F
Chieffo, 2013	Edwards SAPIEN/ Edwards SAPIEN XT 23/26 mm Delivery system of 18/19/22/24 F	Medtronic Core Valve 26/29 mm Delivery system of 18 F/21 F
Choice, 2014	Edwards SAPIEN XT 23/26/29 mm Delivery system of 16-20 F	Medtronic Core Valve 23/26/29/31 mm Delivery system of 18 F
Nombela-Franco, 2013	Edwards SAPIEN XT 26 mm	Medtronic Core Valve 26 mm
D′Ascenzo, 2013	Edwards SAPIEN/ Edwards SAPIEN XT 23/26/29 mm Delivery system of 19/22/24 F	Medtronic Core Valve 26/29/31 mm Delivery system of 18 F/21 F
Watanabe, 2013	Edwards SAPIEN 23/26 mm Delivery system of 19/22 F	Medtronic Core Valve 26/29 mm Delivery system of 18 F

Table 3
Baseline and interventional features of patients (all data are reported as percentages or median with first and third quartiles)

	6 studies, 1903 patients
Age (years):mean(range)	82 (81-83)
women	42% (36%-53%)
Diabetes Mellitus	28% (27%-29%)
Previous myocardial infarction	12% (11%-17%)
Ejection fraction less than 35%	14.5 %(14%-17%)
Severe renal disease	16% (11%-39%)
Logistic Euroscore	22 (21-22)
STS score	8 (7.5-8.5)
Annulus (mm)	22 (21-23)
Prosthesis diameter (mm)	
23	15 %(4%-18%)
26	50%(44%-51%)
29	33%(31%-37%)
31	2 %(1%-2%)

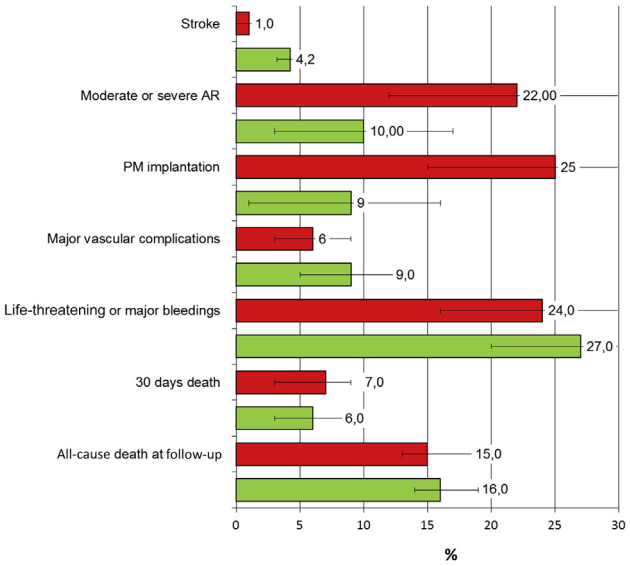
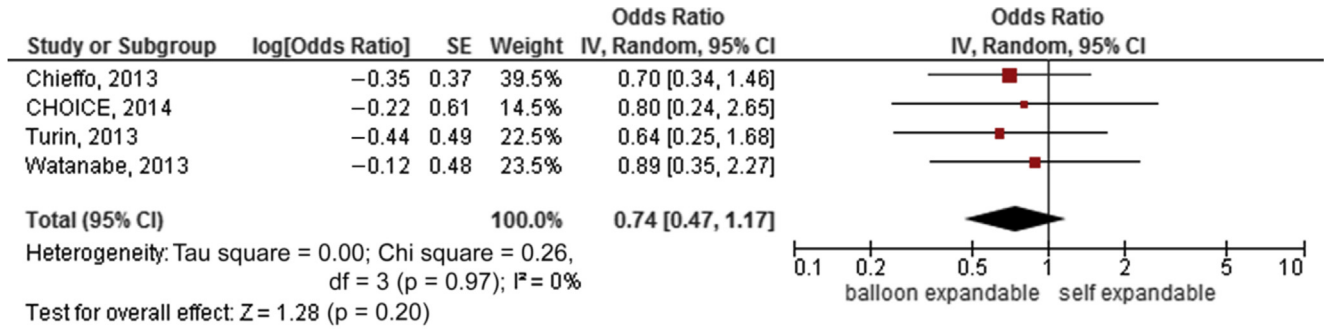


Figure 2. Rates of inhospital complications—all-cause death at 30 days and at follow-up in balloon-expandable and self-expandable valves. PM = pacemaker implantation.

larger diameters, probably related to similar reasons. It should be remembered, however, that AR remains difficult to be assessed.

Implantation of a self-expanding valve has been related to higher rates of atrioventricular blocks requiring a pacemaker. This result is confirmed in the present study and may be explained because of the different valve designs. The self-expanding prosthesis has a stabilizing nitinol frame that exerts greater radial forces on the left bundle branch, which runs superficially just below the endocardium in the uppermost part of the leftward ventricular septum.[25] To maintain hemodynamic efficacy, the frame of the self-expanding valve is dependent on its firm self-expansion to avoid recoil and paravalvular regurgitation, and ongoing compressive forces are needed to achieve greater prosthetic stability. Although this complication does not affect prognosis,[8] it may increase costs and length of hospitalizations, as the hazard of subsequent complications.[26,27]



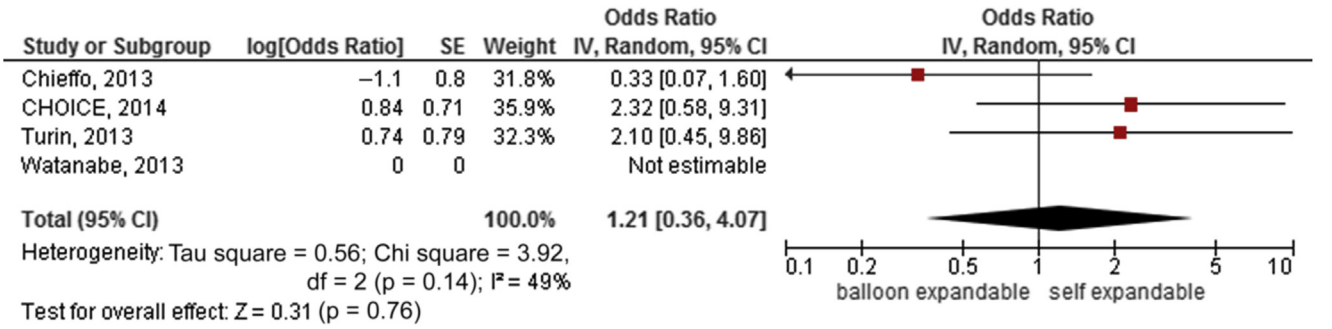
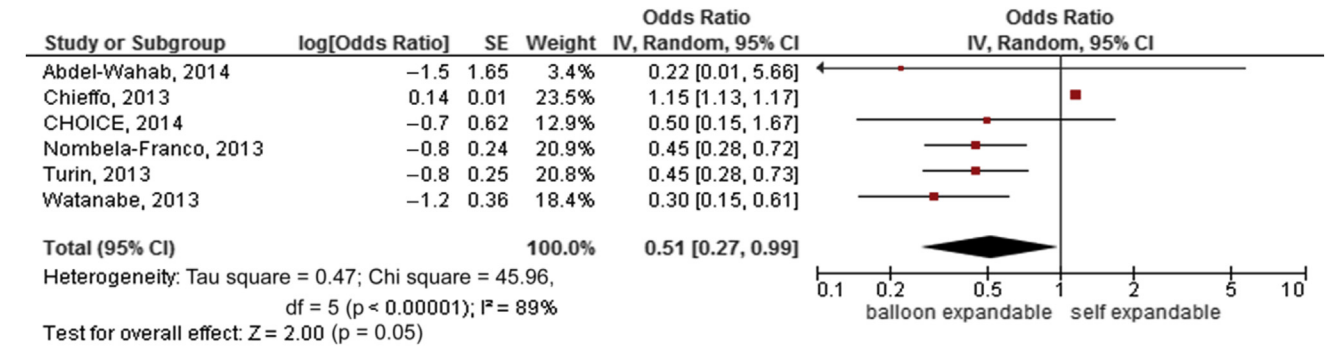


Figure 3. Pooled analysis of risk of 30-day death *(top)* and stroke *(bottom)*.



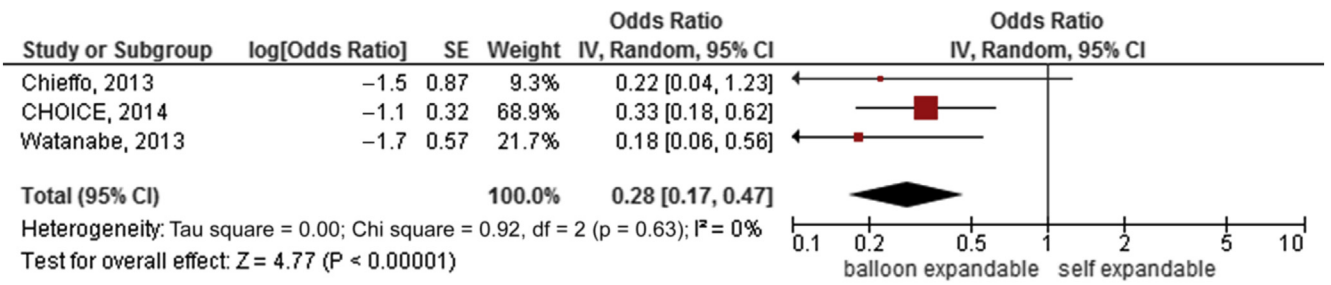


Figure 4. Pooled analysis of risk of moderate or severe aortic regurgitation at 30-day death *(top)* and pacemaker implantation *(bottom)*.

No differences for stroke were reported in the present analysis with balloon-expandable devices. Catheter manipulations of the calcified and diseased aortic valve may cause embolization of aortic debris or thrombotic material resulting in stroke or TIA,[28,29] but this does not appear to depend on differences between self- or balloon-expandable devices.

Thirty-day and 1-year death rates did not differ between the 2 valves. Many explanations may be provided: although higher rates of AR may exert a detrimental effect on prognosis for patients treated with self-expanding devices, follow-up is still limited (no >1 year) not allowing definitive conclusions.

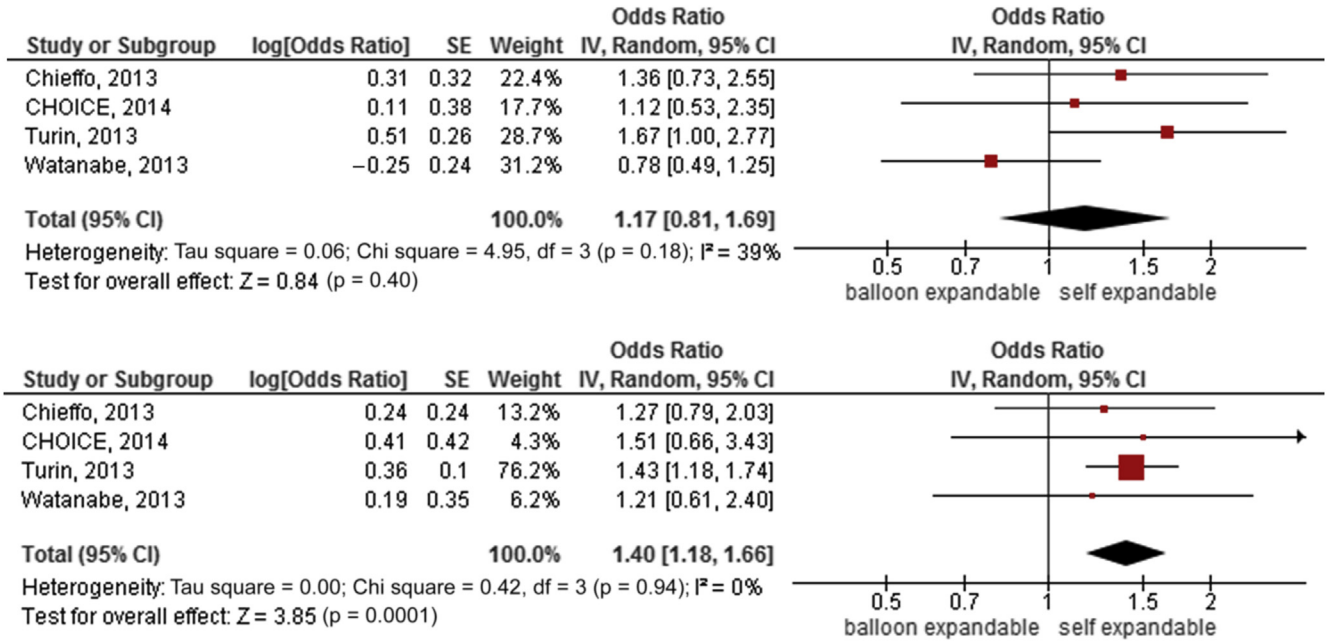


Figure 5. Pooled analysis of risk of major vascular complications *(top)* and life-threatening and major bleedings *(bottom)*.

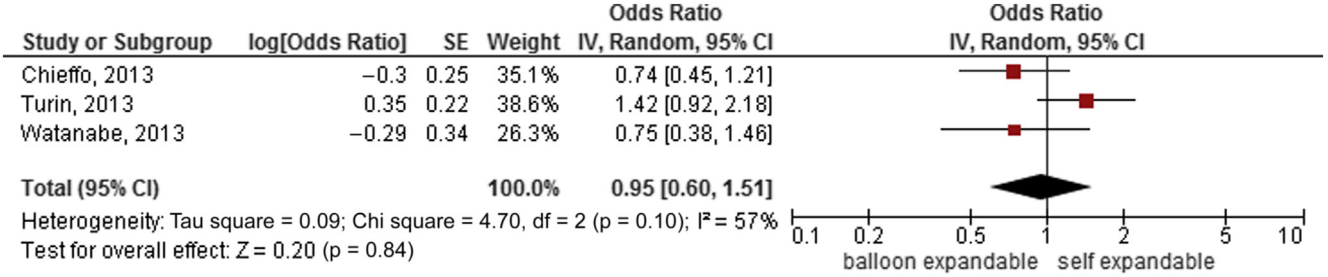


Figure 6. Pooled analysis of death at follow-up.

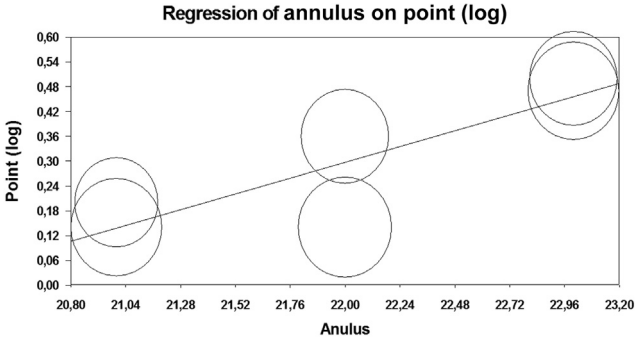


Figure 7. Meta-regression analysis for annulus diameter on aortic regurgitation (beta 0.15; p <0.001).

The present analysis has many limitations. From a methodologic point of view, we included both observational studies, although adjusted with multivariate analysis, and randomized controlled trials, consequently dealing with different level of evidence. Moreover, from a clinical point of view, in each study, AR was assessed through echocardiography, with the well-known limitations of this operator-dependent assessment and without an independent core laboratory assessing AR. Finally, in each study, outcomes were reported with Valve Academic Research Consortium (VARC) definition increasing reproducibility of these results.

Disclosures

The authors have no conflicts of interest to disclose.

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